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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,001	10/28/2003	Bernward Scholkens	02481.1707-01	3677

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EXAMINER
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HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/694,001

Applicant(s)

SCHOLKENS ET AL.

Examiner

Raymond J. Henley III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16,20-25,30-35 and 71-93 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16,20-25,30-35,71 and 74-91 is/are rejected.
- 7) ☒ Claim(s) 71-73 and 91-93 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/22/04 & 1/27/05.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**CLAIMS 16, 20-25, 30-35 AND 71-93 ARE PRESENTED FOR EXAMINATION**

Applicants' Information Disclosure Statement filed September 22, 2004 and Supplemental Information Disclosure Statement and Amendment filed January 27, 2005 have been received and entered into the application.

Accordingly, claims 17-19, 26-29 and 36-70 have been canceled; the specification at page 1 and claims 16, 30 and 35 have been amended; and claims 71-93 have been added. Also, as reflected by the attached, completed copies of forms PTO-1449 and PTO/SB/08, the Examiner has considered the cited references.

In view of the above amendments, the objection to the specification and rejection of claims 16-18, 20-28 and 30-34 under 35 U.S.C. § 112, first paragraph, as set forth in the previous Office action dated July 29, 2004 at pages 3-4, are withdrawn. Also, Applicants' remarks at pages 8-12 have persuaded the Examiner that the presently claimed subject matter would not have been obvious. Accordingly, the rejection of claims 16-18, 20-28 and 30-34 under 35 U.S.C. § 103, as set forth in the previous Office action at pages 4-6, is withdrawn.

***Restriction Requirement***

At page 7 of their remarks, Applicants have requested reconsideration of the withdrawal from consideration of, *inter alia*, claims 19 (now claim 78) and 35. In light of the allowable status of the subject matter of claim 16, the requirement to elect a single species of cardiovascular event (see the Office action dated June 1, 2004 at page 3, third paragraph), is withdrawn. All claims currently present in the application have been examined to their full extent.

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### ***Specification***

It is anticipated that this application will be allowed upon Applicants' response to the present Office action. Several informalities are noted in the specification and Applicants' cooperation is requested in fully reviewing the application papers and correcting any errors of which Applicants may become aware. Examples of such errors are "nephropathie" (page 3, last line of the second full paragraph and page 4, line 2 of the third full paragraph; should read ---nephropathy---); "revascularisation" (page 5, line 3 of the first paragraph; should read ---revascularization---); "atery" (page 5, line 3 of the first full paragraph; should read ---artery---); and "diabetis" (page 5, line 1 of the penultimate paragraph; should read ---diabetes---).

### ***Claim Objection***

Claims 71 and 91 are objected to because the claims from which these claims depend do not provide clear antecedent basis for "another antihypertensive".

Claims 72, 73, 92 and 93 are objected to as depending from a rejected base claim, but are otherwise in condition for allowance.

### ***Claim Rejection - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16, 20-25, 30-35, 71 and 74-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of

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what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention.” (MPEP 2173).

The term "derivative" in the expression “ramipril, ramiprilat, or a pharmaceutically acceptable derivative thereof” (claims 16 and 77) is a relative term which renders the claim indefinite. In particular, “derivative” does not particularly point out the degree or type of derivation that a given compound may have in relation to either ramipril or ramiprilat and still be considered a “derivative” as intended by Applicants.

Applicants have failed to provide a *specific* definition for this term in the present specification. In the present specification at the paragraph bridging pages 8-9, it is stated:

“Pharmaceutically acceptable derivatives of RAS inhibitors are understood to include physiologically tolerable salts of RAS inhibitors, such physiologically tolerable salts are understood as meaning both their organic and inorganic salts, such as are described in Remington’s Pharmaceutical Sciences (17<sup>th</sup> Edition, page 1418 (1985))...”

Such disclosure, however, does not render the claims definite. Words and phrases in the claims must be given their “plain meaning” as understood by one having ordinary skill in the art *unless* defined by Applicants in the specification with “reasonable clarity, deliberateness and precision”. (MPEP 2111.01). Here, Applicants' definition of “derivatives” is not reasonably clear, deliberate or precise because the definition employs the terms “include” and “such as” and thus does not specify what other compounds may be considered as being RAS inhibitor derivatives.

Lacking a clear meaning of the term “derivative”, the skilled artisan would not be

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reasonably apprised of the metes and bounds of the subject matter for which Applicant seeks patent protection and it would be left to a subjective interpretation, either on the part of Applicants or another individual, of whether a particular compound of interest was included in or excluded by the present claims. Such a circumstance is inconsistent with the tenor or express requirements of 35 U.S.C. § 112, second paragraph and thus, the claims are deemed properly rejected.

In order to overcome the present rejection, it is suggested that Applicants amend the appropriate claims to expressly include the expression "physiologically tolerable salts" and/or those specifically disclosed derivatives set forth in the present specification at the paragraph bridging pages 8-9.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, contact the Electronic Business

Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "R. J. Henley III".

Raymond J Henley III

Primary Examiner

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April 15, 2005